DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 9, 2011, has been entered.

2. Claims 1-50 have been cancelled. New Claims 51-65 are pending and are considered in this Office action.

3. Applicants are informed that the objection and rejections of the previous Office action **are moot** in view of the cancellation of prior Claims 1, 2, 6-25 and 27-50.

Sequence Rule

4. (**Prior objection**) The objection to the specification for lacking a sequence list is withdrawn in view of the sequence list, filed on December 6, 2006.

Claim Rejections - 35 USC 112, first paragraph-Written description

5. The following is a quotation of the first paragraph of 35 USC 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 51-65 are rejected under 35 USC 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In making a determination as to whether a claimed invention has been adequately described, the courts have identified certain elements that may be considered. Among those elements are the knowledge in the particular field, the extent and content of the prior art, the maturity of the technology, and predictability of the aspect at issue. See e.g., *Capon v. Eshhar*, 76 U.S.P.Q. 2d 1078, at 1085 (CAFC 2005). For a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, **where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus** ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

7. Claims 51-60 are directed a monoclonal antibody or fragment comprising an amino acid sequence of SEQ ID NOs: 43, 44, 45, 46 or 47. Claims 61-65 are directed to a pharmaceutical composition comprising a monoclonal antibody or fragment comprising an amino acid sequence of SEQ ID NOs: 43, 44, 45, 46 or 47.

8. First, the art does not consider that the claimed antibody and fragment, described solely by amino acid sequence of VH or VL, is adequately described according to the definition of an antibody. The following is a recitation of a definition of antibody from The Illustrated Dictionary of Immunology.

"Antibodies are glycoprotein substances produced by B lymphoid cells in response to stimulation with an immunogen. Antibodies possess the ability to **react specifically and selectively with the antigenic determinant or epitope** eliciting their production or **with an antigenic determinant closely related to the homologous antigen**" (The Illustrated Dictionary of Immunology (1995, CRC Press, Inc. Boca Raton FL; JM Cruse and RE Lewis eds., (See attachment to the Office action dated May 21,2009)

Based on the definition of an antibody, an antibody is defined by its specificity of reacting to antigen. In the present case, without adequate description of the specificity, one of ordinary skill in the art cannot envision what is the claimed antibody or fragment thereof.

9. Secondly, the term "a pharmaceutical composition" indicates that the claimed antibody is intended to be used in clinical application. A pharmaceutical composition requires showing clinical benefit. In supporting the claims, the specification shows a few antibody fragments that recognize HERV antigens (human endogenous virus), can cross-reaction with gp120.

10. However, as indicated above, the claims fail to indicate what specific antigen(s) or microbial pathogen(s) the claimed antibody or fragment reacts or neutralizes. The specification has not shown that the claimed antibody or fragment can be used for treating any specific diseases or viral infections, providing clinical benefit. It is known in the art that an antibody has ability to cross-react with other "with an antigenic determinant closely related to the homologous antigen" by definition. It is also well known in the art that an antibody has the ability to recognize or bind, or cross react with more than one protein that share a homologous sequence; see e.g. Bost *et al.,* Golding, H. *et al.* and Langat DK, *et al* , cited in the previous office action dated May 21, 2009; Para 31. However, the art does not teach an antibody can be a medicine for treating all diseases if the antibody is capable of reacting with any antigen. Thus, one of ordinary sill in the art cannot what specific diseases the claimed antibody or fragment thereof treats.

11. Finally, the state of the art indicates that it is not certain if all antibody or antibody fragment can be a medicine (pharmaceutical composition), providing clinical benefit. For even a well-defined antibody, the art teaches it is not certain if can be a medicine, providing clinical benefit. For instant, most trials of antibody therapy for treating viral infection, such as for HAV, HBV and HIV infection, have been shown to have no treatment benefit, due to lack of effective antibodies and other obstacles to maintaining an effective concentration of antibody *in vivo*, thus failing to compete with viral replication. see e.g. Keller, Table 1, p. 603 (Keller, CLINICAL MICROBIOLOGY REVIEWS, Oct. 2000, p. 602–614 Vol. 13, No. 4)

12. Given the uncertainty of antibody therapy, and also given a lack of indication of the specificity of the claimed antibody fragment, one of ordinary skill in the art cannot envision what specific diseases the claimed antibody fragment is capable of treating. The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the claimed antibody fragments and pharmaceutical composition.

Remarks

13. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/
Primary Examiner, Art Unit 1648